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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/624,583	07/22/2003	Angelika Maria Domschke	2C03.1-172	7521

23506 7590 06/28/2004

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MARIETTA, GA 30067

EXAMINER

ZALUKAEVA, TATYANA

ART UNIT	PAPER NUMBER
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1713

DATE MAILED: 06/28/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/624,583

Applicant(s)

DOMSCHKE ET AL.

Examiner

Tatyana Zalukaeva

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 22 July 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 12-18 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 12-18 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>05/17/04</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claim Rejections - 35 USC § 103

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

3. Claims 12-18 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Hennink et al (U.S. 5,019,100).

Hennink discloses eye lens made of a polymer, which was prepared by a curing of a polymer network composed of polymethacrylate, which contains chemically bound ethylene oxide units, as hydratable groups to render the hydratability of a polymer, the ethylene oxide is in the form of oligomer blocks. (see abstract). The properties related to water permeability can be further modified by including other types of hydratable groups in the network, such as **N-vinylpyrrolidone** (col. 4, lines 31-44). The amount of ethylene oxide ranges from 10-80% by weight (col.4, lines 5,6) . The ethylene oxide units are presented in a form of oligomeric blocks containing 5-200 ethylene oxide units.

Especially interesting is an example 1 in col.8 both in terms of components taken for copolymerization, and the mode of the process.

This example relates to preparing a preparation for manufacturing **eye lenses** and also to manufacturing an eye lens. A preparation which consists of 43.8% by weight of PLURONIC PE 6400-IEM, (PEO-PPO-PEO) 38.2% by weight of NVP, 15.0% by weight of water, 2.0% by weight of QUANTACURE BTC and 1.0% by weight of antioxidant is introduced into a suitable glass mould . Subsequently, the mould is irradiated for 1.5 minutes with a conventional **2 kW high-pressure mercury lamp**. The lens formed is removed from the mould and finally irradiated for 15 minutes once again to complete the polymerization.

This swellability can be controlled by adding 0-45% by weight of water to PLURONIC PE 6400-IEM, the swellability of the **cured gel** can be accurately controlled to from 38 to 46% by weight. The process is performed at room temperature.

Since the numerical values of cloud points of the compositions are not presented by Applicants, therefore, in considering limitations of the instant claim 1 "below the cloud point" and around the cloud point", Examiner relied on the data from the instant specification, such as, the temperature of 33-36°C at which the composition "was left for polymerization", as described on page 13, line 2 of the Specification. Therefore, the temperature of Hennink satisfies the temperature as instantly claimed.

The instant claims are product-by-process claims. Because of the nature of product-by process claims, the Examiner cannot ordinarily focus on the precise difference between the claimed product and the disclosed product. It is then Applicants'

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burden to prove that an unobvious difference exists. See *In re Marosi*, 218 USPQ 289, 292-293 (CAFC 1983).

See also footnote 11 O.G. Notice 1162 59-61, wherein a 35 USC 102/103 rejection is authorized in the case of product-by-process claims because the exact identity of the claimed product or the prior art product cannot be determined by the Examiner.

Furthermore, the patentability of the product relies on the product per se, not on the process by which it is made. There is no evidence, or no reason to believe that the process of polymerization as instantly claimed produces a different product, that of a polymerization of Hennik, consult *In re Thorpe*, 227 USPQ 964 (CAFC 1985), wherein the Examiner rejected product-by-process claims over a product, which although prepared in a different manner, appeared to be the same (prima facie) as the claimed product.

In the instant case no Graham vs. John Deere analysis was made but rather the test set out in MPEP 706.03(e) and *In re Marosi* was applied while explaining why the claimed product does not patentably distinguish over the prior art under 35 USC 102/103.

See also footnote 11 O.G. Notice 1162 59-61, wherein a 35 USC 102/103 rejection is authorized in the case of product-by-process claims because the exact identity of the claimed product or the prior art product cannot be determined by the Examiner, or *In re Brown*, 173 USPQ 685 (CCPA 1972), the Court of Customs and Patent Appeals (CCPA) explicitly approved the 102/103 rejection of a product-by-

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process claim over a reference which showed a product which appeared to be identical or only slightly different from the claimed product.

4. Applicants are reminded to update the continuity data.
5. Other prior art of record shown in PTOL-892 reflects the state of the art.
6. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Tatyana Zalukaeva whose telephone number is (571) 272-1115. The examiner can normally be reached on 9:00 - 5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, David Wu can be reached on (571) 272-1114. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Tatyana Zalukaeva
Primary Examiner
Art Unit 1713



June 24, 2004